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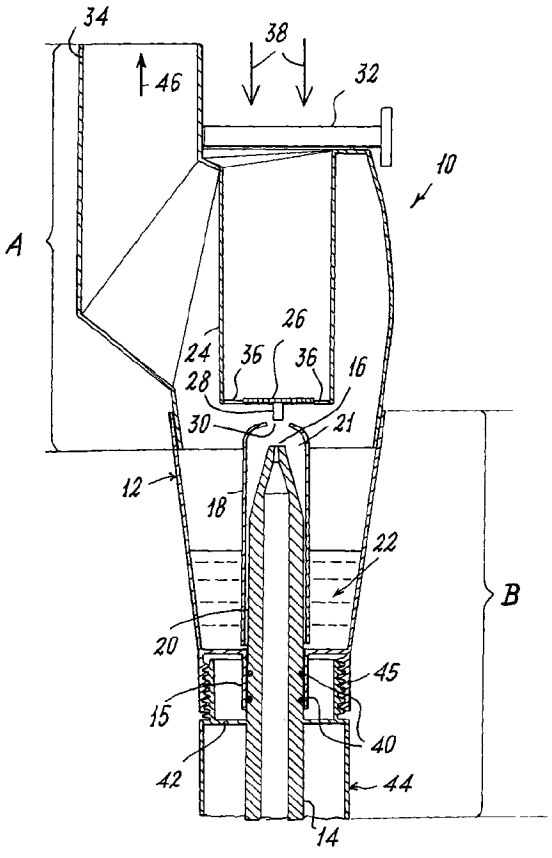
(54) Title: NEBULIZING CHAMBER FOR AEROSOL THERAPY



(57) Abstract: The nebulizing chamber (10) for aerosol therapy comprises a tube (14) fed at a first end with compressed air, the tube (14) being constricted internally at its second end prior to the relative exit orifice (16) to obtain a venturi effect. The orifice (16) of the tube (14) emerges from the free surface of a solution (22) of an aerosol therapy medicament, a nozzle (18) being concentrically mounted on the second end of the tube (14) such that between the tube (14) and nozzle (18) there remains an interspace (20) which communicates with the solution (22). A flow breaker device (26) is provided above the orifice (30) of the nozzle (18). The chamber (10) is provided with an exit (34) for the formed aerosol and an inlet (24) for entry of external air as a result of suction exerted by the patient on the exit (34). Means are provided to vary the distance between the orifice (16) of the compressed air tube (14) and the orifice (30) of the nozzle (18).

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NEBULIZING CHAMBER FOR AEROSOL THERAPY

The present invention relates to a nebulizing chamber for aerosol therapy.

Known nebulizing chambers for aerosol therapy are of plastic construction and use the venturi principle, in particular the so- called double venturi, in the sense that the air originating from a compressor is passed at high velocity through a small-diameter tube constricted internally (to form the venturi) and terminating with an orifice which emerges from the free surface of a solution of an aerosol therapy medicament contained in a reservoir. A nozzle (also known as a pisper) is mounted concentrically on the end of said tube such that between the two there is an interspace communicating lowerly with the solution contained in the reservoir. The compressed air leaving the orifice of said tube causes the particles or droplets of the medicament solution to be sucked upwards through said interspace, to form an upwardly directed stream of solution particles, which leaves the nozzle orifice. The stream of solution particles formed in this manner is atomized (to form the aerosol) by causing the stream to strike against a flow breaker device positioned above the nozzle orifice. The flow breaker device is positioned at, but without completely closing, the lower end of a conduit through which external air can enter the chamber following inhalation by the patient on an aerosol exit conduit.

As known to the expert of this sector, the characteristic parameters of a therapeutic aerosol are the mass median aerodynamic diameter (indicated by the initials MMAD), the geometric standard deviation (indicated by the initials GSD) and the nebulization rate.

The MMAD provides an indication of the average dimensions of the particles forming the aerosol, this identifying the region of the patient's air passageways in which the nebulized medicament will deposit.

The GSD enables the degree of dispersion of the solution particle dimensions within the distribution to be evaluated.

Finally, the nebulization rate is essentially an index of the mass of medicament nebulized per unit of time.

The MMAD and the GSD can both be obtained from the aerosol particle diameter distribution: the MMAD is in fact the aerodynamic diameter to which 50% of the aerosol particle diameter distribution corresponds; the GSD can be calculated from the particle diameter distribution graph, if the distribution is sufficiently linear between 10% and 90%, i.e. if the distribution is Gaussian, by using suitable

extrapolation calculation methods (see ISO 9276-2).

The medical literature has established that, for therapeutic purposes, those regions of a patient's respiratory tract reachable by the aerosol are related to the dimensions of the medical solution particles inhaled. More precisely, aerodynamic particle diameters greater than 5 microns are adequate for treatment of the upper air passages; diameters between 2 and 6 microns for the tracheobronchial region; diameters between 0.5 and 3 microns for alveolar administration. Reference should be made to the following texts for further details:

- International Commission on Radiological Protection (1994): Human Respiratory Tract Model for Radiological Protection. Annals of the ICRP Vol. 24, No. 1-3 Elservier Science Inc. Tarrytown NY

- Heyder J., Gebhart J., Rudolf G., Schiller C.F. e Stahlhofen W. (1986): Deposition of particles in the human respiratory tract in the size range 0.005-15ìm Journal of Aerosol Science 17(5):811-825.

- Stahlhofen W., Rudolf G., and James A.C. (1989): Intercomparison of Experimental Regional Deposition Data. Journal of Aerosol Medicine 2(3): 285-308.

From the aforegoing it is evident that to treat respiratory affections it is important that the dose of suitable medicament is administered only into the therapeutically appropriate region of the respiratory tract, to prevent wastage of medicament in addition to undesired systemic effects. To achieve this, a nebulizing chamber must be used which is able to generate an aerosol of the precise particle size distribution characteristics.

An object of the present invention is therefore to provide a nebulizing chamber for aerosol therapy which enables the MMAD to be varied.

It is also important that a nebulizing chamber has a nebulization rate suitable for the type of patient to be treated. In this respect, although it is true that increasing the nebulization rate accelerates the therapy, a high nebulization rate, although suitable for normal adult patients, can be excessive for determined patients such as children or seriously asthmatic patients, to the extent of making correct administration of the medicament difficult.

Another object of the invention is therefore to provide a nebulizing chamber of the aforestated type in which the nebulization rate can be varied.

As a nebulizing chamber for aerosol therapy is often used for domiciliary treatment by non-expert persons and can be used repeatedly for different respiratory pathologies, a further object of the invention is to provide a chamber of the aforesaid

type in which the aerosol characteristics (particle size distribution and nebulization rate) can be varied on the basis of the patient's therapeutic needs in a very simple manner within the ability of any patient.

The aforestated first object is attained by the nebulizing chamber of the present invention, characterised by comprising means which enable the distance between the air feed tube orifice and the nozzle orifice to be varied. In this respect it has been verified that varying this distance varies the MMAD of the solution particles.

The means for varying said distance conveniently comprise means for fixing the nozzle to the reservoir containing the medicament solution for generating the aerosol, and seal means between the air fed tube and the casing of said aerosol reservoir, through which casing said tube passes, the said seal means being of the type which enables the length of that portion of air feed tube inserted into said reservoir to be varied.

The aforestated second object is attained by providing a device for adjusting the flow of external air entering the chamber as a result of inhalation by the patient, this enabling the nebulization rate of the nebulizing chamber to be adjusted.

From the aforegoing it will be apparent that the nebulizing chamber which attains the two aforestated objects also enables the aforesaid final object to be attained.

Preferably, the nebulizing chamber is formed in two parts, of which a lower part contains the solution of medicament for aerosol therapy and comprises the compressed air feed tube and the relative nozzle, whereas the upper part comprises the flow breaker diaphragm, the inlet enabling external air to enter the chamber following inhalation by the patient, and the aerosol exit conduit, the two parts being removably connected together.

The fact of forming the nebulizing chamber in two parts (as just described) can be used to vary the distance between the nozzle orifice and the flow breaker diaphragm, the two said parts of the chamber being able to be formed and connected together in such a manner as to be able to obtain different distances between the nozzle orifice and the flow breaker device, i.e. hence also serving to vary the MMAD.

The invention will be more easily understood from the ensuing description of one exemplifying embodiment thereof. In this description reference is made to the accompanying drawing, in which the single figure represents a very schematic vertical section through a nebulizing chamber of the invention, the section being taken on a plane passing through the axis of the compressed air feed tube and also comprising the axis of the external air entry tube and the exit tube for the aerosol

formed.

Observing the figure it can be seen that the nebulizing chamber 10 is composed of two parts, namely an upper part A and a lower part B. To enable the chamber 10 to be used, the parts A and B have to be connected together (in Figure 1 the chamber is shown mounted, ready for use). The connection between the two parts A and B can be achieved in various ways, for example by a screw connection, by a bayonet connection or by a snap clip connection.

As can be seen, the lower part B comprises a casing 12, shaped as an upwardly flared cup, which acts as the reservoir for the aerosol medicament solution. The base of the reservoir 12 is traversed by a tube 14 for feeding compressed air generated by a compressor (not shown) of the type conventionally used for aerosol equipment. From the base of the reservoir 12 there downwardly extends a coaxial sleeve 15 which defines the hole through which the air tube 14 passes. This latter presents two circumferential grooves into which respective O- rings 40 are inserted to form a seal by cooperating with the sleeve 15.

From the figure it can also be seen that a concentric tubular element 44 is fixed to the compressed air tube 14 by a concentric circular baffle 42. Below the baffle 42 the tubular element 42 has a diameter substantially equal to that of the base of the reservoir 12, whereas above it it presents an outer lateral thread which mates with a corresponding thread provided inside a skirt 45 extending downwards from the base of the reservoir 12. As can be further seen from the figure, the upper end of the tube 14 is tapered both externally and internally (to obtain the so-called double venturi effect), the tube 14 finally terminating with an orifice 16.

A nozzle 18 is mounted concentrically on the upper end of the tube 14 so that between the two there remains an interspace 20 which lowerly communicates with the solution 22 which occupies the reservoir 12 to a determined level. The nozzle 18 is fixed relative to the reservoir 12 (for example by ribs not shown in the figure), whereas the tube 14 through which the compressed air is fed can be inserted to a greater or lesser extent into the reservoir 12 to vary the distance between the orifice 16 of the air tube 14 and the orifice 30 of the nozzle 18. The free space 21 between the upper end of the compressed air tube 14 and the corresponding upper inner surface of the nozzle 18 is of variable volume as is apparent from the aforegoing, this volume indicated by 21 acting as the preatomization chamber.

Above and coaxial with the nozzle 18 there is disposed a conduit 24 through which external air enters the chamber as a result of aspiration by the patient. The lower

end of the conduit 24 is partly closed by a bar-shaped flow breaker diaphragm 26, the two ends of which are connected to the conduit 24. At the upper end of the conduit 24 there is provided a flow regulator cock shown very schematically and indicated overall by 32. The cock 32 enables the nebulization rate to be continuously adjusted from a minimum value to a maximum value, in order to adapt the aerosol leaving the chamber to the respiration characteristics of the patient. In the figure the arrows 38 indicate the entry of external air.

In the illustrated example the bar 26 carries a peg 28, coaxial to the nozzle 18, which extends towards the orifice 30 of the nozzle 18.

The nebulizing chamber 10 is completed by an aerosol exit channel 34, to the upper end of which there can be connected a usual mouthpiece, a respiratory mask or a nasal adapter (not shown), through which the patient can inhale the aerosol.

As already stated, one way of varying the MMAD of the particles of the aerosol produced by the chamber 10 is to vary the distance between the orifice 16 of the compressed air tube and the orifice 30 of the nozzle 18. To achieve this variation continuously (with reference to the figure), it is sufficient to rotate the tubular element 44 (to which the compressed air tube 14 is fixed) in one direction or the other with one hand, so screwing it into or unscrewing it from the skirt 45 fixed to the reservoir 12.

The tubular element 44 also acts as a handgrip for the patient.

According to one embodiment of the present invention, the chamber dimension in a direction transverse to the nozzle axis is greatest at or close to the orifice 30 of the nozzle 18.

According to another embodiment of the invention, not shown, the chamber presents at least one vertical section, taken on a plane passing through the nozzle axis, having an outer profile at least approximately elliptical, the minor axis (horizontal with the chamber maintained vertical) of the ellipse lying at or in proximity to the nozzle orifice.

Although already apparent from the aforegoing, the operation of the nebulizing chamber 10 will now be briefly described.

After pouring the prescribed quantity of medicament solution 22 into the cup-shaped reservoir 12 (having obviously separated the two parts A and B of the chamber 10) and reassembling the two parts A and B, the compressed air compressor (not shown) is operated to feed compressed air into the lower end of the tube 14. As already stated, the outflow of compressed air from the orifice 16 of the

compressed air tube 14 causes particles of solution to be drawn through the interspace 20, to form an ascending stream of air and solution particles which flows from the orifice 30 of the nozzle 18 and strikes the diaphragm 26, to cause atomization of the solution particles. As a result of the sucking action (indicated by the arrows 46) exerted by the patient through the upper end of the aerosol exit conduit 34 - causing external air (indicated by the arrows 38) to be drawn through the upper aperture (provided with a regulator cock 32) of the conduit 24 - the aerosol stream, formed as a result of the impact of the solution particles against the diaphragm 26 and their mixing with the air entering through the conduit 24 (and passing through the apertures 36), is directed towards the exit channel 34, to finally reach the patient (who exerts the sucking action) via a mouthpiece, mask or nasal adapter (not shown).

From the aforegoing it is apparent that the particle size characteristics of the aerosol can be varied very simply directly by the patient. By simply acting on the tubular element 44 (by screwing or unscrewing it), the patient can cause the orifice 16 of the compressed air tube 14 to approach the orifice 30 of the nozzle 18 or to withdraw from it, so adjusting the particle size of the aerosol to adapt it to specific requirements. In particular, indications (numerical or symbolic) can be conveniently provided on the tubular element 44 together with a reference mark on the skirt 45 to indicate to the patient which level of the respiratory tract is reached by the aerosol particles drawn in.

CLAIMS

1. A nebulizing chamber (10) for aerosol therapy, comprising a tube (14) fed at a first end projecting outwards from the chamber (10) with compressed air, the tube (14) being constricted internally at its second end prior to the relative exit orifice (16) to obtain a venturi effect, the orifice (16) of the tube (14) emerging from the free surface of a solution (22) of an aerosol therapy medicament contained in a reservoir (12) provided in the chamber (10), a nozzle (18) being concentrically mounted on the second end of the tube (14) such that between the tube (14) and nozzle (18) there remains an interspace (20) which communicates lowerly with the solution (22), a flow breaker device (26) being provided above the orifice (30) of the nozzle (18), the chamber (10) being provided with an exit (34) for the formed aerosol and an inlet (24) for entry of external air as a result of suction exerted by the patient on the exit (34), characterised in that means are provided to vary the distance between the orifice (16) of the compressed air feed tube (14) and the orifice (30) of the nozzle (18).

2. A nebulizing chamber (10) for aerosol therapy as claimed in claim 1, wherein the means for varying the distance between the orifice (16) of the air tube (14) and the orifice (30) of the nozzle (18) comprise means for fixing the nozzle to the reservoir (12) containing the medicament solution (22), and means (40) for sealing the joint between the casing of the reservoir (12) and the air tube (14) which passes through this casing.

3. A nebulizing chamber (10) for aerosol therapy as claimed in claim 2, wherein the means for varying the distance between the orifice (16) of the air tube (14) and the orifice (30) of the nozzle (18) also comprise a sleeve (15) projecting downwards from the base of the reservoir (12), the compressed air tube (14) being insertable through the sleeve, the sealing means comprising at least two O-rings (40) insertable into circular grooves provided in the outer surface of the tube (14) and cooperating with the inner surface of the sleeve (15).

4. A nebulizing chamber as claimed in claim 3, wherein an internally threaded skirt (46) extends downwards coaxially to the sleeve (15) from the base of the reservoir (12), there being fixed to the compressed air tube (14) an externally threaded concentric tubular element (44) to be screwed into the skirt (46).

5. A nebulizing chamber (10) for aerosol therapy as claimed in claim 1, wherein the flow breaker device comprises a diaphragm (26) disposed above the orifice (30) of the nozzle (18).

6. A nebulizing chamber (10) for aerosol therapy as claimed in claim 5, wherein

the flow breaker diaphragm (26) is disposed at an inner end of a conduit (24) without however closing said end, the other end of the conduit (24) being open towards the outside to enable external air to enter following suction exerted by the patient on the aerosol exit (34).

7. A nebulizing chamber (10) for aerosol therapy as claimed in claim 5, wherein from that face of the flow breaker diaphragm (26) facing the orifice (30) of the nozzle (18) there extends, coaxial to this latter, a peg 28.

8. A nebulizing chamber (10) for aerosol therapy as claimed in claim 1, wherein a regulator device (32) is provided for the external air entering the chamber (10) through the external air entry aperture (24).

9. A nebulizing chamber (10) for aerosol therapy as claimed in claim 8, wherein the external air flow regulator device comprises a regulator cock (32).

10. A nebulizing chamber (10) for aerosol therapy as claimed in claim 1, comprising two parts (A, B), of which a lower part (B) comprises the reservoir (12) for the aerosol medicament solution (22) and the compressed air feed tube (14) with the relative nozzle (18), whereas the upper part (A) comprises the flow breaker diaphragm (26), the entry aperture (24) enabling the external air to enter the chamber (10) following the suction exerted by the patient, and the aerosol exit conduit (34), the two parts (A, B) being removably connectable together.

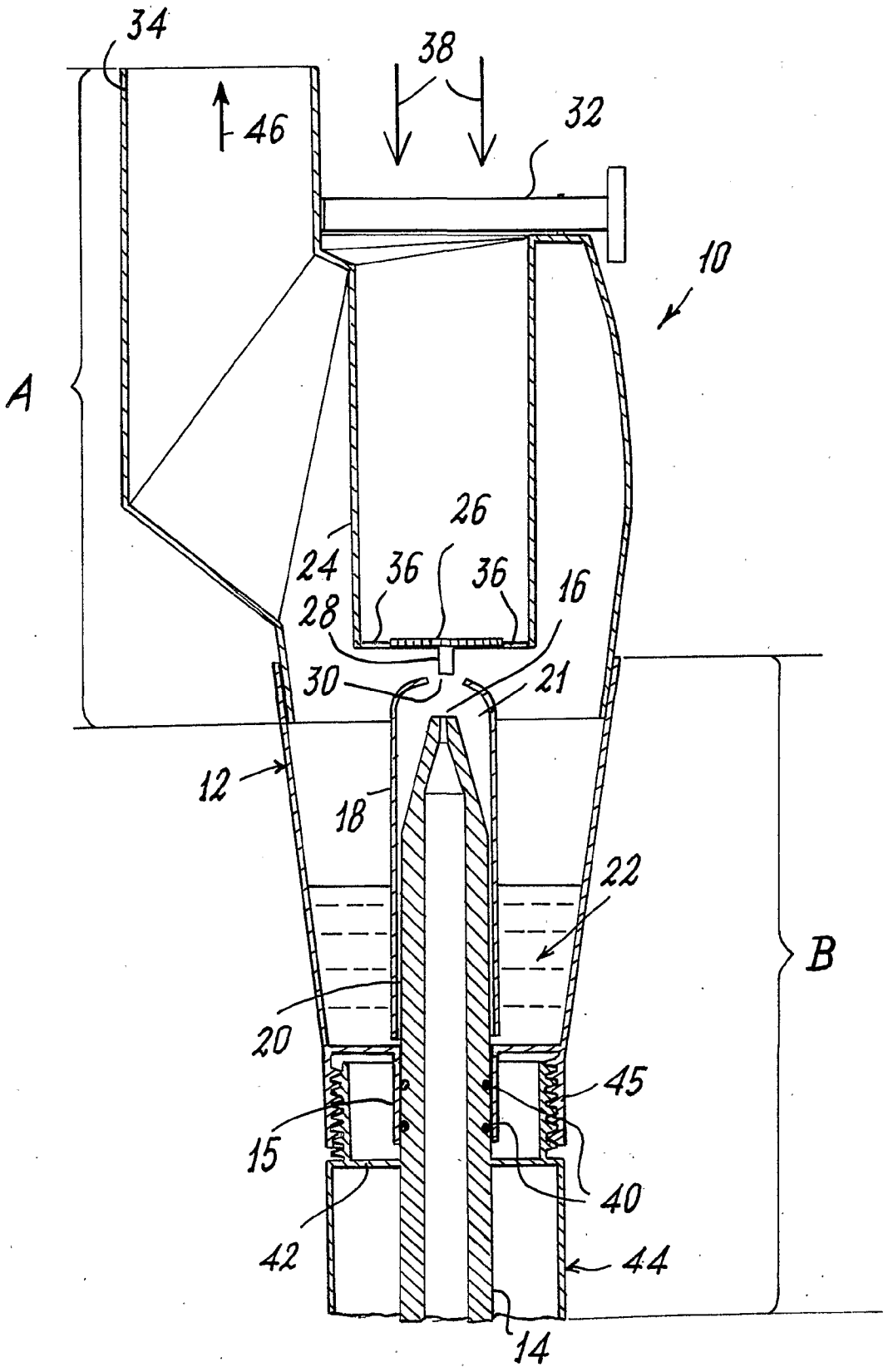
11. A nebulizing chamber (10) for aerosol therapy as claimed in claim 9, wherein the connection between the two parts (A, B) is of screw type.

12. A nebulizing chamber (10) for aerosol therapy as claimed in claim 10, wherein the connection between the two parts (A, B) is of bayonet type.

13. A nebulizing chamber (10) for aerosol therapy as claimed in claim 10, wherein the connection between the two parts (A, B) is of snap clip type.

14. A nebulizing chamber for aerosol therapy as claimed in claim 1, wherein the chamber dimension in the direction transverse to the nozzle axis is greatest at said nozzle.

15. A nebulizing chamber for aerosol therapy as claimed in claim 1, wherein at least one vertical section through the chamber taken on a plane passing through the axis of the nozzle (18) has an outer profile which is at least approximately elliptical, with the minor axis of the ellipse lying at or in proximity to the orifice (30) of the nozzle (18).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